K111294 JAN 27 2012

510(k) Summary
for the
Santorini Corpectomy Cage System

This 510(k) summary for the Santorini Corpectomy Cage System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :
Nancy Giezen
K2M, Inc.
Telephone: 703-777-3155

Date Prepared: 12/22/11

2. Tradename:	Santorini Corpectomy Cage System
Common Name:	Vertebral Body Replacement Device
Classification Name:	Spinal intervertebral body fixation orthosis (888.3060)
Device Product Code:	MQP
Regulatory Class:	Class II

3. Predicate or legally marketed devices which are substantially equivalent :

- Aleutian Spacer System (K051454)
- Globus Xpand-R (K060665)
- Medtronic Verte-stack (K030736)
- OEC Rezaian (K841189)
- DePuy Surgical Titanium Mesh (K003043)
- Osteotech VBR (003155)
- Theken VuMesh (K070381)
- Interpore Cross Expandable PEEK VBR (K040928)

4. Description of the device:

The Santorini Corpectomy Cage System consists of a hollow tube structure manufactured from Medical Grade PEEK (Polyetheretherketone). The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates.

Materials: The devices are manufactured from Medical Grade PEEK (Polyetheretherketone) OPTIMA® LT1 (Invibio™) per ISO 10993-1 USP Class VI and ASTM F2026. Tantalum beads /rods to be Grade UNS R05200, UNS R05400 according to ASTM F560. Other materials include titanium, in accordance with ASTM F1492 and F67.

Function: The system functions as a vertebral body replacement device to provide support and stabilization of the thoraco-lumbar segments of the spine.

5. Intended Use:

The Santorini Corpectomy Cage System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, damaged or unstable vertebral bodies due to tumor or trauma (ie. fracture). The Santorini Spinal System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The Santorini device may be used with allograft or autograft.

For all the above indications the Santorini implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The Santorini Corpectomy Cage System was mechanically tested and compared to predicate devices. The Santorini Corpectomy Cage System performed equally to or better than these systems in static compression, static torsion, dynamic compression, dynamic torsion, subsidence and expulsion in accordance with ASTM standards F2077 and F2267. The design features and sizing of the components were also compared and the Santorini Corpectomy Cage System was found to be substantially the same as these systems.

There are no significant differences between the Santorini Corpectomy Cage System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 27 2012

K2M, Inc.
% Ms. Nancy Giezen
751 Miller Drive, SE, Suite F1
Leesburg, Virginia 20175

Re: K111294
Trade/Device Name: Santorini Corpectomy Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 22, 2011
Received: December 23, 2011

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111294

Device Name: Santorini Corpectomy Cage System

Indications for Use:

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rescription Use X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use __ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111294